

PERFORMANCE QUALIFICATION

Carried out the following Checks for the Performance of the DiaSys SYS 200 Pro (Sl. No. SYS20220807) at Origin Path Lab, HB Twin Tower 2nd, 4rth floor, Netaji Subhash palace, Delhi

Run the Calibration for End Point, Kinetic & Fixed-Time Kinetic Calibration was Successful.

Run the Trulab N & Trulab P control for Different Parameters.

Quality Checks for which the performance is OK & the Results are Satisfactory, within the Specified range.

Precision Checks: Carried out the Precision checks for different Parameters for which Precision was found to be satisfactory.

Linearity Check: Carried out the linearity check for different parameters for which linearity was found to be satisfactory.

For DiaSys Diagnostics India Pvt. Ltd.,

Asmat Sami



Asmat Sami

RSM (NORTH)

Date: 02/09/2022

OPERATIONAL QUALIFICATION

For Operational Qualifications carried out the following checks on the *SYS 200 Pro* (Sl. No. SYS20220807)

Checked the overall System Mechanism found the Robotic Arm (Sample/ Reagent Arm), Vertical and Horizontal Movement In/Out) Performance is ok.

Software Checks: Carried out the check for Calibration, Control, Assay, Results, Data & the performance is ok.

Checked all the Operational Qualifications & found the functioning is Satisfactory.

For DiaSys Diagnostics India Pvt. Ltd.,

Asmat Sami



Asmat Sami

RSM (NORTH)

Date: 02/09/2022

INSTALLATION QUALIFICATION

The Installation for SYS 200 Pro (Sl. No. SYS20220807) at Origin Path Lab, HB Twin Tower 2nd, 4rth floor, NetaJI Subhash palace, Delhi

Checked all the Mechanisms through the Software like Robotic Arm (Sample/Reagent Arm), Reagent Tray & Sample Tray Movement for different position.

Robotic Arm: Carried out the Adjustment for Robotic Arm for Wash station for Sample, Reagent, Cuvettes positions.

Lamp: The Photometer all channels are within range for all wavelengths.

Checked the system performance for different Parameters like End Point, Kinetic & Fixed-Time Kinetic.

Calibration & Control for all the Assays was satisfactory.

Carried out the Precision Check for above parameters which was also good.

For DiaSys Diagnostics India Pvt. Ltd.,

Asmat Sami



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RSM (NORTH)

Date: 02/09/2022

Calibration Certificate

Following voltages have been checked & adjusted on DiaSys SYS 200 Pro (Sl. No. SYS20220807) at Origin Path Lab, HB Twin Tower 2nd, 4th floor, Netaji Subhash palace, Delhi

Calibration Report:

System voltages are in the specified range – Checked by Digital Multimeter are as below:

S.No.	Module	Observed Value	Acceptable Range
1	Power supply board o/p	+24.1 VDC	+24.0 +/- 0.5 VDC
		+05.0 VDC	+05.0 +/- 0.2 VDC
2	Lamp voltage	+12.1 VDC	12.0 +/- 0.5 VDC

System Temperature values are in the specified range –Checked by Digital Thermometer are as below:

S.No.	Module	Observed Value	Acceptable Range
1	Reaction Disk Temp	37.0 C	37.0 C +/- 0.3 C

Photometer Adjustment Values are within range as recommended:

S.No.	Module	Observed Value	Acceptable Range
1	ADC Count for all Wavelengths	10,240 to 10,300	8000 to 18,000

- All other mechanisms have been checked through field service program & Software, found OK.
- Performed calibration for End Point, Kinetic & Fixed Time Kinetic. Run control & sample. Results were satisfactory.
- Next Calibration will be performed on 01/09/2023.

For DiaSys Diagnostics India Pvt. Ltd.




Asmat Sami

Date: 02/09/2022

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